REMARKS

The Applicants thank the Examiner for the examination to date and respectfully request reconsideration of the present application in view of the foregoing amendments and the reasons that follow.

I. Status of the Claims

Independent claim 15 is amended to incorporate the recitation of the specific embodiments of the FGF-7 expression accelerators in claim 16; support for the term "FGF-7 expression accelerator" can also be found in, *inter alia*, second full paragraph on p. 4 of the Specification as filed. Claim 16 is thus cancelled, and the Applicants reserve the right to pursue the subject matter of the cancelled claim in a continuation application. The dependencies of claims 17 and 19 have also been amended to reflect the change. New claim 21 is added to recite a specific embodiment of claim 15, in which the composition consists essentially of the recited one or more FGF-7 expression accelerators. Support therefor can be found in the disclosure in, *inter alia*, Example 1 of the present Specification (*see* particularly the part of the disclosure wherein such an accelerator is introduced in an aqueous medium). No new matter is introduced, and claims 15 and 17-21 are currently pending to be examined on their merits.

II. Claim Rejection – 35 U.S.C. § 112

Claims 15 and 18 are rejected under 35 U.S.C. § 112, ¶ 1, as allegedly failing to comply with the written description requirement. The Applicants respectfully traverse.

While not acquiescing to the grounds of the rejections, independent claim 15 is amended to recite specific embodiments of the FGF-7 expression accelerators. In view of the foregoing amendments, the Applicants traverse the Office's apparent position that (1) without a recitation of a chemical structure, the written description requirement is not met (Office Action, p. 7); and (2) the Specification only supports the recitation of adenosine and N-ethylcarboxyamido-adenosine (Office Action, p. 4).

The Applicants respectfully submit that the Office's reliance on and conclusion from *Eli Lilly* are improper. The Federal Circuit has recently clarified the law regarding written description in *Faulkner-Gunter Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006). Specifically, the court held:

> 1) examples are not necessary to support the adequacy of a written description;
> 2) the written description standard may be met even when actual reduction to practice is absent; and
> 3) there is **no** *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure

(bold emphasis added). *See* Section IIC of the opinion.

Thus, the Office's reliance on the holding of *Eli Lilly* with respect to a DNA to reach the conclusion that the presently claimed methods involving a chemical composition related to a FGF-7 expression accelerator requires a recitation of a structure is improper. In fact, as described above, the Office's position is in conflict with the Federal Circuit case law, which imposes no such requirement in the present case.

The Applicants further traverse the Office's assertion on p. 4 of the Office Action that the present Specification supports only the adenosine and N-ethylcarboxyamido-adenosine embodiments, and the recitation in (A) in present claim 15 is "merely a functional language" (Office Action, p. 5). At the outset, present claim 1 is amended to clarify that the recitation in (A) describes what the composition **is**, which description is further evidenced in the last "wherein" clause in claim 15, reciting the specific embodiments of what the composition is – i.e., one that "comprises one or more FGF-7 expression accelerator." Thus, the Applicants respectfully submit that the Office's characterization of the recitation in present claim 15 as a functional language is moot in view of the foregoing amendments.

Contrary to the Office's assertion, the Applicants respectfully submit that the present Specification sufficiently supports more than just adenosine and N-ethylcarboxyamido-adenosine. The Federal Circuit has clarified issues particularly relevant for the present application and enunciated in *Faulkner-Gunter Falkner v. Inglis*, 448 F.3d at 1366 (Fed. Cir.

2006) that an absence of examples does not render written description inadequate. The court favorably cites *LizardTech Inc. v. Earth Resource Mapping, PTY Inc.*, 424, F.3d 1336 (Fed. Cir. 2005), explaining that the specification is written for a person skilled in the art and it is unnecessary to spell out every detail of the invention, only enough is required to convince a person of skill in the art that the inventor possessed the invention and to enable the person to make and use the invention without undue experimentation. The court further clarifies, as provided in *Capon v. Eshlar*, 418 F. 3d 1349 (Fed. Cir. 2005) that the 'written description' requirement implements the principle that a patent must describe the technology to be patented. This requirement is to satisfy the inventor's obligation to disclose the technologic knowledge upon which the application is based and to demonstrate that the patentee was in possession of the invention.

At the outset, the present Specification provides more than "an absence of examples" as in *Falko-Gunter Falkner* – the Office acknowledges the present Specification has disclosed at least two; *see* Office Action, p. 4. Furthermore, the present Specification provides that the other embodiments recited in claim 15, particularly CCPA, C1-IB-MECA, etc., are "**adenosine analogues**." *See* first full three paragraphs on p. 8 of the Specification as filed. The Office has acknowledged that the embodiments related to adenosine have met the written description requirement. *See* Office Action, p. 4. Thus, in view of the disclosure of the present Specification, one of ordinary skill in the art clearly would appreciate that the present inventors were in possession of the present invention.

Therefore, at least in view of the foregoing, the Applicants respectfully submit that the present claims comply with the written description requirement and thus respectfully request that the rejection be withdrawn.

III. Claim Rejection – 35 U.S.C. § 102

Claims 15-20 are rejected under 35 U.S.C. § 102, as allegedly being anticipated by US 2004/0171693 ("Gan"). The Applicants respectfully traverse.

Gan fails to anticipate the presently claimed invention because it relates to the use of creatine (a compound NOT within the scope of the present claims) to increase DNA synthesis (a use NOT within the scope of the present claims). For these two reasons, Gan cannot anticipate.

To the extent the PTO is relying upon Gan's recitation of adenosine for "energy increasing" activity as an inherent teaching of growing hair, the applicants traverse. Concerning inherency, the presently claimed methods recite administration to a subject "in need thereof." The PTO cannot rely upon inherency where, as here, the phrase "in need thereof" is tied to a distinct use recited in the preamble of the claim which is not found in the prior art. This point was established in the Federal Circuit's 2001 holding in *Rapaport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001). The *Rapaport* holding was summarized as follows in *Jansen v. Rexall Sundown*, 342 F.3d 1329 (Fed. Cir. 2003):

> A similar issue arose in *Rapoport,* an interference proceeding before the PTO's Board of Patent Appeals and Interferences. The count in that case read as follows:
> A method *for treatment of sleep apneas* comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof *to a patient in need of such treatment* ....
> 254 F.3d at 1056 (emphases added). On appeal we gave weight to the ordinary meaning of the preamble phrase "for treatment of sleep apneas," interpreting it to refer to sleep apnea, *per se,* not just "symptoms associated with sleep apnea." *Id.* at 1059. Rapoport argued that the count was unpatentable on the ground that a prior art reference disclosed that a form of the compound recited in the claim could be administered, not for treatment of sleep apnea itself, but for treatment of anxiety and breathing difficulty, a symptom of apnea. *Id.* at 1061. We rejected that argument, stating, "There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition.*" *Id.* (emphasis added). Thus, the claim was interpreted to require that the method be practiced with the intent to achieve the objective stated in the preamble.

Thus, even where the patient population overlapped, the court found no inherency based on the different purpose of the claimed method. The reference failed to teach an intent to cure the recited condition in the claim.

Claim 21 is separately patentable in light of its use of the phrase "consisting essentially of", which further distinguishes Gan's use of creatine.

Therefore, at least in view of the foregoing, the Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

The Applicants believe that the present application is now in condition for allowance and thus respectfully request favorable reconsideration of the application.

The Office is invited to contact the undersigned by telephone if a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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